

STATEMENT OF EMERGENCY

907 KAR 1:039E

(1) This emergency administrative regulation is being promulgated in conjunction with 907 KAR 1:038E, Hearing program coverage provisions and requirements to establish program integrity provisions and safeguards in order to ensure appropriate utilization of services as well as to protect the health, safety, and welfare of Medicaid recipients. Additionally, the amended administrative regulation is being promulgated to establish that Medicaid Program coverage of the services under this administrative regulation is contingent upon the receipt of federal approval and federal funding in order to prevent expending Kentucky taxpayer funds when federal matching funds are not provided.

(2) This action must be taken on an emergency basis to prevent a potential loss of state funds.

(3) This emergency administrative regulation shall be replaced by an ordinary administrative regulation filed with the Regulations Compiler.

(4) The ordinary administrative regulation is identical to this emergency administrative regulation.

Steven L. Beshear
Governor

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Policy and Operations

4 (Emergency Amendment)

5 907 KAR 1:039E. Hearing Program reimbursement provisions and require-
6 ments~~[Payments for hearing services]~~.

7 RELATES TO: KRS 205.520, 334.010, 334.040, 334.200, 334A.020(5), 42 C.F.R.
8 447.200, 204

9 STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3)

10 NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family
11 Services, Department for Medicaid Services, has responsibility to administer the Medi-
12 caid program~~[of Medical Assistance]~~. KRS 205.520(3) authorizes the cabinet, by admin-
13 istrative regulation, to comply with any requirement that may be imposed, or opportunity
14 presented, by federal law to qualify for federal Medicaid funds~~[for the provision of medi-~~
15 ~~cal assistance to Kentucky's indigent citizenry]~~. This administrative regulation establish-
16 es the reimbursement provisions and requirements for covered audiology services,
17 hearing instruments, and related items provided to a Medicaid recipient who is not en-
18 rolled with a managed care organization~~[method for determining amounts payable by~~
19 ~~the department for hearing services]~~.

20 Section 1. Definitions. (1) "Audiologist" is defined by KRS 334A.020(5).

21 (2) "CPT code" means a code used for reporting procedures and services performed

1 by medical practitioners and published annually by the American Medical Association in
2 Current Procedural Terminology.

3 ~~(3) ["Comparable instrument" means an instrument falling within the general classifi-~~
4 ~~cations of fitting type, for example, body, behind the ear, in the ear, or eyeglasses.~~

5 ~~(3)]~~ "Department" means the Department for Medicaid Services.

6 (4) "Federal financial participation" is defined in 42 CFR 400.203.

7 (5) "Healthcare Common Procedure Coding System" or "HCPCS" means a collec-
8 tion of codes acknowledged by the Centers for Medicare and Medicaid Services (CMS)
9 that represents procedures or time.

10 (6) "Hearing instrument" is defined by KRS 334.010(4).

11 (7) "Managed care organization" means an entity for which the Department for Medi-
12 caid Services has contracted to serve as a managed care organization as defined in 42
13 C.F.R. 438.2.

14 (8) "Medically necessary" means that a covered benefit is determined to be needed
15 in accordance with 907 KAR 3:130.

16 (9) "Participating audiologist" means an audiologist who is:

17 (a) Enrolled in the Medicaid program pursuant to 907 KAR 1:672;

18 (b) Currently participating in the Medicaid program pursuant to 907 KAR 1:671; and

19 (c) Meets the audiologist requirements established in 907 KAR 1:038.

20 (10) "Participating specialist in hearing instruments" means a specialist in hearing in-
21 struments who is:

22 (a) Enrolled in the Medicaid program pursuant to 907 KAR 1:672;

23 (b) Currently participating in the Medicaid program pursuant to 907 KAR 1:671; and

1 (c) Meets the specialist in hearing instruments requirements established in 907 KAR
2 1:038.

3 (11) "Recipient" is defined by KRS 205.8451(9).

4 (12)[(5)] "Specialist in hearing instruments" is defined by KRS 334.010(9).

5 (13) "Usual and customary charge" means the uniform amount that a provider bills to
6 the general public for a specific covered benefit.

7 Section 2. General Reimbursement Requirements. (1)(a) For the department to re-
8 imburse for a service or item the service or item shall be:

9 1. Provided:

10 a. To a recipient under the age of twenty-one (21) years, including the month in
11 which the recipient becomes twenty-one (21); and

12 b. By a provider who is:

13 (i) Enrolled in the Medicaid program pursuant to 907 KAR 1:672;

14 (ii) Currently participating in the Medicaid program pursuant to 907 KAR 1:671; and

15 (iii) Authorized to provide the service in accordance with 907 KAR 1:038;

16 2. Covered in accordance with 907 KAR 1:038; and

17 3. Medically necessary.

18 (b) In accordance with Section 3(3) of 907 KAR 17:010, a provider of a service to an
19 enrollee shall not be required to be currently participating in the Medicaid program if the
20 managed care organization in which the enrollee is enrolled does not require the
21 provider to be currently participating in the Medicaid program.

22 (2)(a) If a procedure is part of a comprehensive service, the department shall:

23 1. Not reimburse separately for the procedure; and

1 2. Reimburse one (1) payment representing reimbursement for the entire
2 comprehensive service.

3 (b) A provider shall not bill the department multiple procedures or procedural codes if
4 one (1) CPT code or HCPCS code is available to appropriately identify the
5 comprehensive service provided.

6 (3) A provider shall comply with:

7 (a) 907 KAR 1:671;

8 (b) 907 KAR 1:672; and

9 (c) All applicable state and federal laws.

10 (4)(a) If a provider receives any duplicate or overpayment from the department,
11 regardless of reason, the provider shall return the payment to the department.

12 (b) Failure to return a payment to the department in accordance with paragraph (a) of
13 this section may be:

14 1. Interpreted to be fraud or abuse; and

15 2. Prosecuted in accordance with applicable federal or state law.

16 (c) Non-duplication of payments and third-party liability shall be in accordance with
17 907 KAR 1:005.

18 (d) A provider shall comply with KRS 205.622.

19 (5) The department shall not reimburse for:

20 (a) A service with a CPT code that is not listed on the Department for Medicaid
21 Services Hearing Program Fee Schedule; or

22 (b) An item with an HCPCS code that is not listed on the Department for Medicaid
23 Services Hearing Program Fee Schedule.

1 Section 3. Audiology Service Reimbursement. The department shall reimburse a par-
2 ticipating audiologist for an audiology service at the lesser of the:

3 (1) Audiologist's usual and customary charge for the service; or

4 (2) The reimbursement established on the Department for Medicaid Services Hear-
5 ing Program Fee Schedule for the service.

6 Section 4. Hearing Instrument Reimbursement. (1) The department shall reimburse a
7 participating specialist in hearing instruments or participating audiologist for a hearing
8 instrument at the lesser of the:

9 (a) Provider's usual and customary charge for the hearing instrument; or

10 (b) The reimbursement established on the Department for Medicaid Services Hear-
11 ing Program Fee Schedule for the hearing instrument.

12 (2) A hearing examination of a recipient by a physician and a recommendation for a
13 hearing instrument for the recipient by an audiologist shall:

14 (a) Be required for the department to cover a hearing instrument; and

15 (b) Occur prior to the fitting of a hearing instrument.

16 (3)(a) Except for an ear mold, an invoice for a hearing instrument, related supply, or
17 accessory shall be submitted with the corresponding claim:

18 1. To the department; and

19 2. By the participating audiologist or participating specialist in hearing instruments
20 who supplied the hearing instrument, related supply, or accessory.

21 (b) The department shall not require a participating audiologist or participating spe-
22 cialist in hearing instruments to submit an invoice for an ear mold.

23 Section 5. Ear Mold Reimbursement. (1) The department shall reimburse a partici-

participating audiologist or participating specialist in hearing instruments for an ear mold at the lesser of the:

(a) Provider's usual and customary charge for the ear mold; or

(b) The reimbursement established on the Department for Medicaid Services Hearing Program Fee Schedule for the ear mold.

(2) The department shall limit reimbursement for an ear mold, in conjunction with an ear examination, to:

(a) One (1) ear mold per six (6) month period for a child aged three (3) years or under; or

(b) One (1) ear mold per twelve (12) month period for a child who is at least four (4) years of age.

Section 6. Reimbursement for Hearing Instrument Batteries. (1) The department shall reimburse a participating audiologist or participating specialist in hearing instruments for a hearing instrument battery at the lesser of the:

(a) Provider's usual and customary charge for the hearing instrument battery; or

(b) The reimbursement established on the Department for Medicaid Services Hearing Program Fee Schedule for the hearing instrument battery.

(2) The department's reimbursement for hearing instrument batteries shall be limited to fifty-two (52) batteries per hearing instrument when dispensed with a:

(a) New hearing instrument; or

(b) Replacement hearing instrument.

Section 7. Replacement Cord Reimbursement. The department shall reimburse a participating audiologist or participating specialist in hearing instruments for a replace-

ment cord at the lesser of the:

(1) Provider's usual and customary charge for the replacement cord; or

(2) The reimbursement established on the Department for Medicaid Services Hearing Program Fee Schedule for the replacement cord.

Section 8. Hearing Instrument Repair Reimbursement. The department shall reimburse a participating audiologist or participating specialist in hearing instruments for hearing instrument repair at the lesser of the:

(1) Provider's usual and customary charge for the hearing instrument repair; or

(2) The reimbursement established on the Department for Medicaid Services Hearing Program Fee Schedule for the hearing instrument repair.

Section 9. Not Applicable to Managed Care Organizations. A managed care shall not be required to reimburse the same amount as established in this administrative regulation for a service or item covered pursuant to 907 KAR 1:038 and this administrative regulation.

Section 10. Federal Approval and Federal Financial Participation. The department's reimbursement for services pursuant to this administrative regulation shall be contingent upon:

(1) Receipt of federal financial participation for the reimbursement; and

(2) Centers for Medicare and Medicaid Services' approval for the reimbursement.

Section 11.~~[Section 2. Reimbursement to an Audiologist. The department shall reimburse a participating audiologist at usual and customary actual billed charges up to the fixed upper limit per procedure established by the department at sixty-five (65) percent of the median billed charge using 1989 calendar year billed charges.~~

Section 3. Hearing Instrument Reimbursement. (1) If a manufacturer of a hearing instrument billed to the department submits a price schedule which includes the manufacturer's invoice price of the hearing instrument, the department shall reimburse the participating specialist in hearing instruments at the lesser of:

(a) The manufacturer's invoice price plus a professional fee of:

1. \$150 for the first (one (1) ear) hearing instrument; and

2. Fifty (50) dollars for the second (two (2) ears or binaural) hearing instrument if two (2) hearing instruments are dispensed on the same date;

(b) The actual specialist in hearing instruments' cost plus a professional fee of:

1. \$150 for the first (one (1) ear) hearing instrument; and

2. Fifty (50) dollars for the second (two (2) ears or binaural) hearing instrument if two (2) hearing instruments are dispensed on the same date; or

(c) The suggested retail price submitted by the manufacturer for the hearing instrument.

(2) If a manufacturer of a hearing instrument billed to the department has not submitted a price schedule which includes the manufacturer's invoice price for the hearing instrument, the department shall reimburse the participating specialist in hearing instruments at the lesser of:

(a) The lowest price submitted for a comparable hearing instrument plus a professional fee of:

1. \$150 for the first (one (1) ear) hearing instrument; and

2. Fifty (50) dollars for the second (two (2) ears or binaural) hearing instrument if two

(2) hearing instruments are dispensed on the same date;

1 ~~(b) The actual specialist in hearing instruments' cost plus a professional fee of:~~
2 ~~1. \$150 for the first (one (1) ear) hearing instrument; and~~
3 ~~2. Fifty (50) dollars for the second (two (2) ears or binaural) hearing instrument if two~~
4 ~~(2) hearing instruments are dispensed on the same date; or~~
5 ~~(c) The lowest suggested retail price submitted by a manufacturer for a comparable~~
6 ~~instrument.~~

7 ~~Section 4. Replacement Cord Reimbursement. The department shall reimburse for a~~
8 ~~replacement cord at the specialist in hearing instruments' cost plus a professional fee~~
9 ~~set at \$21.50.~~

10 ~~Section 5. Hearing Instrument Repair Reimbursement. The department shall reim-~~
11 ~~burse a specialist in hearing instruments for a hearing instrument repair:~~

12 ~~(1) On the basis of the manufacturer's charge for repair or replacement of parts;~~
13 ~~(2) Plus the specialist in hearing instruments' cost for postage and insurance relative~~
14 ~~to the repair;~~
15 ~~(3) Plus a professional fee of \$21.50; and~~
16 ~~(4) Not to exceed the price of a new hearing instrument.~~

17 ~~Section 6.] Appeals. A provider may appeal a department decision as to the applica-~~
18 ~~tion of this administrative regulation in accordance with 907 KAR 1:671.~~

19 Section 12. Incorporation by Reference. (1) The "Department for Medicaid Services
20 Hearing Program Fee Schedule", December 2013, is incorporated by reference.

21 (2) This material may be inspected, copied, or obtained, subject to applicable copy-
22 right law, at the Department for Medicaid Services, 275 East Main Street, Frankfort,
23 Kentucky, Monday through Friday, 8 a.m. to 4:30 p.m. or online at the department's

- 1 Web site at <http://www.chfs.ky.gov/dms/incorporated.htm>.
- 2 (Recodified from 904 KAR 1:039, 5-2-86; Am. 17 Ky.R. 572; eff. 10-14-90; 25 Ky.R. 1255;
- 3 1661; eff. 1-19-99; 34 Ky.R. 1823; 2112; eff. 4-4-08.)

907 KAR 1:039E

REVIEWED:

Date

Lawrence Kissner, Commissioner
Department for Medicaid Services

APPROVED:

Date

Audrey Tayse Haynes, Secretary
Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 1:039E
Cabinet for Health and Family Services
Department for Medicaid Services
Agency Contact Person: Stuart Owen (502) 564-4321

- (1) Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes the reimbursement provisions for Medicaid hearing services and related.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with federal and state laws that require provision of hearing services for the KY Medicaid recipients who are eligible for hearing services.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing hearing service reimbursement provisions.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the authorizing statutes by establishing hearing service reimbursement provisions.
- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: The amendment establishes that the coverage provisions are contingent upon the receipt of federal approval and federal funding; inserts program integrity requirements and safeguards; incorporates by reference a Hearing Program Fee Schedule which lists covered CPT codes and HCPCS codes along with corresponding reimbursements; eliminates the prior upper payment limit which was sixty-five (65) percent of the median billed charge (for a service) using 1989 calendar year billed charges; eliminates reimbursement provisions that are now addressed on the aforementioned fee schedule; clarifies that an individual remains eligible for services in the month that they become twenty-one (21); inserts requirements that were previously stated in a hearing services manual; inserts ear mold, hearing instrument, and hearing instrument battery reimbursement limits. This administrative regulation is being promulgated simultaneously with a companion administrative regulation (907 KAR 1:038E, Hearing program coverage provisions and requirements) necessary to be promulgated at the same time as this administrative regulation.
 - (b) The necessity of the amendment to this administrative regulation: Establishing that the provisions are contingent upon the receipt of federal approval and federal funding is necessary to prevent Kentucky taxpayer funds from being spent if federal matching funds are not being provided. The program integrity requirements/safeguards are necessary to ensure appropriate utilization of services and to protect the health, safety, and welfare of Medicaid recipients. The upper pay-

ment limit amendment is necessary to equalize provider reimbursement among programs/provider types (physicians and audiologists); and incorporating the fee schedule offers providers a more reader-friendly mechanism for displaying reimbursement. This amended administrative regulation is being promulgated simultaneously with a companion administrative regulation (907 KAR 1:038E, Hearing Program coverage provisions and requirements) as the companion administrative regulation adopts the same fee schedule incorporated by reference into this administrative regulation.

- (c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by preventing a potential loss of state funds, by enhancing program integrity requirements and safeguards for Medicaid recipients, and by equalizing provider reimbursement among programs and provider types.
 - (d) How the amendment will assist in the effective administration of the statutes: This amendment assists in the effective administration of the authorizing statutes by preventing a potential loss of state funds, by enhancing program integrity requirements and safeguards for Medicaid recipients, and by equalizing provider reimbursement among programs and provider types.
- (3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: For calendar year 2012, eleven (11) specialists in hearing instruments billed the Medicaid program [either a managed care organization or “fee-for-service Medicaid (non-managed care)] for services rendered and sixty-nine (69) audiologists billed the Medicaid program. 3,510 individuals (managed care and fee-for-service combined) received services from specialists in hearing instruments in calendar year 2012 and 3,236 individuals (managed care and fee-for-service combined) received services from audiologists during the same period.
- (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
- (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment. No action is necessary to comply with the amendment other than to properly bill for services and adhere to program integrity requirements.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). No cost is imposed by the amendment.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3). Providers should benefit from the fee schedule as it’s a more reader-friendly mechanism with which to view reimbursement. Recipients may benefit from the enhanced program integrity requirements and safeguards.
- (5) Provide an estimate of how much it will cost to implement this administrative regulation:

- (a) Initially: In calendar year 2012, the Department for Medicaid Services (DMS), i.e. “fee-for-service” or “FFS” paid almost \$6,000 in claims to specialists in hearing instruments and Medicaid managed care organizations paid \$342,348 in claims to specialists in hearing instruments. For the same period DMS paid \$13,191 in claims to audiologists and Medicaid managed care organizations paid \$340,513 in claims to audiologists.
- (b) On a continuing basis: DMS anticipates that paid claims (fee-for-service and managed care) in calendar years 2013 and 2014 will be similar to calendar year 2012 expenditures.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX of the Social Security Act and matching state funds appropriated in the biennium budget.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Neither an increase in fees nor funding will be necessary to implement the amendment.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither imposes nor increases any fees.
- (9) Tiering: Is tiering applied? (Explain why tiering was or was not used) Tiering is applied as audiology service coverage and hearing instrument coverage are limited to individuals under twenty-one (21) years of age as this is a component of mandated Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) services pursuant to 42 U.S.C. 1396d(r)(4) and 42 C.F.R. 441.56(c)(1).

FEDERAL MANDATE ANALYSIS COMPARISON

Regulation Number: 907 KAR 1:039E

Agency Contact Person: Stuart Owen (502) 564-4321

1. Federal statute or regulation constituting the federal mandate. 42 U.S.C. 1396d(r)(4), 42 U.S.C. 1396a(a)(30)(A), and 42 C.F.R. 441.56.
2. State compliance standards. KRS 194A.050(1) states, "The secretary shall promulgate, administer, and enforce those administrative regulations necessary to implement programs mandated by federal law, or to qualify for the receipt of federal funds and necessary to cooperate with other state and federal agencies for the proper administration of the cabinet and its programs."
3. Minimum or uniform standards contained in the federal mandate. EPDST hearing coverage must include at least testing and diagnosis and treatment for hearing defects, including hearing aids. Hearing services must also be, "provided—
(i) at intervals which meet reasonable standards of medical practice, as determined by the State after consultation with recognized medical organizations involved in child health care, and
(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition."

Additionally, Medicaid reimbursement for services is required to be consistent with efficiency, economy and quality of care and be sufficient to attract enough providers to assure access to services. 42 U.S.C. 1396a(a)(30)(A) requires Medicaid state plans to:

" . . . provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?
No.
5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. The requirements are not stricter.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation Number: 907 KAR 1:039E

Agency Contact Person: Stuart Owen (502) 564-4321

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services (DMS) is affected by the administrative regulation.
2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. 42 C.F.R. 441.56(c)1.
3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
 - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? DMS anticipates no additional revenue being generated by the amendment.
 - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? DMS anticipates no additional revenue being generated by the amendment.
 - (c) How much will it cost to administer this program for the first year? In calendar year 2012, the Department for Medicaid Services (DMS), i.e. "fee-for-service" or "FFS" paid almost \$6,000 in claims to specialists in hearing instruments and Medicaid managed care organizations paid \$342,348 in claims to specialists in hearing instruments. For the same period DMS paid \$13,191 in claims to audiologists and Medicaid managed care organizations paid \$340,513 in claims to audiologists. DMS anticipates no cost as a result of this amendment. DMS anticipates that paid claims (fee-for-service and managed care) in calendar years 2013 and 2014 will be similar to calendar year 2012 expenditures.
 - (d) How much will it cost to administer this program for subsequent years? In calendar year 2012, the Department for Medicaid Services (DMS), i.e. "fee-for-service" or "FFS" paid almost \$6,000 in claims to specialists in hearing instruments and Medicaid managed care organizations paid \$342,348 in claims to specialists in hearing instruments. For the same period DMS paid \$13,191 in claims to audiologists and Medicaid managed care organizations paid \$340,513 in claims to audiologists. DMS anticipates no cost as a result of this amendment. DMS anticipates that paid claims (fee-for-service and managed care) in calendar years 2013 and 2014 will be similar to calendar year 2012 expenditures.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): _____
Expenditures (+/-): _____
Other Explanation: _____

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

907 KAR 1:039E

Summary of Material Incorporated by Reference

The “Department for Medicaid Services Hearing Program Fee Schedule”, December 2013, is incorporated by reference. This two (2)-page document displays reimbursement for audiology services, hearing instruments, and related items.